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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,122	12/30/2003	Richard L. Boyd	NOR-014CP4 and 286336.153	3280

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EXAMINER	
MONTANARI, DAVID A	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
08/24/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/749,122	BOYD, RICHARD L.	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-34,36-44,46-70,73-75 and 80-84* is/are pending in the application.

4a) Of the above claim(s) *27-34,36-40,42-44,46-48,50-70,73-75,80,81 and 84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,41,49 and 82-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/11/2004+*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group VIII claims 26, 41, 49 and 82-83 in the reply filed on 8/3/2007 is acknowledged. The traversal is on the ground(s) that it would not constitute and undue burden on the Examiner to examine at least Groups VII, VIII and IX together as the search likely to significantly overlap. This is not found persuasive because Groups VII and IX do require significant searching on their own as they are of different scopes than the claims in Group VIII. Group VII further requires cell based administration to a subject and Group IX's scope is drawn specifically to hematopoietic stem cells, which are not needed or required by Group VIII. Searching of these groups because of their divergent scopes would be a search burden upon the Examiner.

Claims 27-34, 36-40, 42-44, 46-48, 50-70, 73-75, 80-81 and 84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/3/2007.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26, 41, 49 and 82-83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of copending Application No. 09/965,395. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the claim 1 recites preventing infection in a patient comprising reactivating the thymus in the 395' application, it would have been obvious to prevent disease using the claimed method in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26, 41, 49 and 82-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

The breadth of the claims encompasses preventing or treating any disease by reactivating the thymus of the patient.

Whereas the nature of the invention is a method of increasing thymus activity (producing more thymocytes) by the disruption of sex steroid influences via chemical castration, the art teaches that such a method would not prevent or treat all disease. At first issue with the claimed method is the breadth of the method, which encompasses treating and preventing any disease by

only reactivating the thymus of the patient. The skilled artisan would question how many diseases are related to the thymus activity and if they are not related to thymus activity then how would the claimed method treat or prevent such a disease? For example the skilled artisan would recognize that Alzheimer's disease, Parkinson's and muscular dystrophy are all diseases, however their respective etiologies and pathologies do not relate/depend upon thymus activity. The art teaches that the pathology of Alzheimer's disease encompasses loss of synapses and neuronal cells and the acquisition of neurofibrillary tangles and beta-amyloid enriched plagues in the brain (2006, Current Pharmaceutical Design, Vol. 12, pgs. 719-738, particularly pg. 720, col. 2 parag. 2). The art continues to teach that with regard to Parkinson's disease there are progressive neuropathological stages that lead to the development of inclusional bodies in the brain which lead to a loss in motor function in the afflicted individual (2004, Cell Tissue Res., Vol. 318, pgs. 121-134, particularly pg. 121 col. 2 parag. 2). Given these teachings in the art, these particular diseases would be outside of the scope of the claimed method, and would raise the issue of unpredictability with respect to treatment/prevention of said diseases. If thymus activity is not related to a disease then how can that disease be treated or prevented using the claimed method? The skilled artisan would be unable to practice the claimed method for its entire breadth.

A second issue of the claimed method resides in dependent claim 49, wherein the reactivation of the thymus is through chemical castration, leading to disruption of sex steroid-mediated signaling to the thymus. Does this chemical castration refer to male or female mice? The working examples do not differentiate between the two and make no mention of the sex of the mice, thus it is assumed by the skilled artisan that only male mice are castrated in the

working examples. If females are contemplated in the specification as also being chemically castrated, the question remains what is being castrated in females that will lead to reactivation of the thymus?

A third issue with the claimed method is the prevention of disease by reactivating the thymus. The claimed method encompasses the prevention of all diseases by thymus reactivation. The skilled artisan would question how the claimed method would prevent disease that are already pre-existing, such as sickle cell anemia, Cri du chat and cystic fibrosis. The art teaches that with regard to sickle cell anemia it is the result of a point mutation in the beta-globin gene, resulting in red blood cells taking on a sickle shape that in turn increases pain in joints and increased incidence of stroke (1996, Science, Vol. 273, pgs. 1386-1389). The art continues to teach that cystic fibrosis is again a genetic disease resulting from a recessive gene that can have hundreds of mutations all resulting in respiratory failure because of a absent or defective ion channel in lung tissue (2001, Free Radical Biology and Medicine, Vol. 30, pgs. 1440-1461, particularly pg. 1440 cols. 1 and 2). The skilled artisan would recognize based upon these teachings in the art that each of these diseases is genetic and pre-exists from birth. The claim method encompasses preventing each of these said diseases, however the skilled artisan would find the claimed method unpredictable with regard that none of said diseases is related to thymus activity and are solely based upon specifically defined genetic mutations.

While the working examples teach that chemical castration disrupts sex steroid-mediated signaling (Examples: 2 and 10-14), the working examples have not demonstrated that a disease is prevented or treated. Each of the working examples is a conception of how the claimed method could be limitedly carried out in murine models of chemical castration and then observing the

effects on particularly defined parameters to be measured, such as thymocyte count. The working examples do not teach or guide the skilled artisan to enable the claimed method to be practiced for its entire breadth, which is treating or preventing any disease by reactivating the thymus. The genus of all diseases both preventable and treatable is simply huge. The skilled artisan would require specific knowledge that each disease is related by etiology to thymic activity and could in turn be both prevented or treated using the claimed method. Thus the skilled artisan would require and undue amount of experimentation without a predictable degree of success to make and use the claimed method.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
Primary Examiner, Art Unit 1632